K103312

MAY 12 2011

510(k) SUMMARY

ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003

May 11, 2011

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo,
192-8507, Japan
Establishment Registration No.: 8010047

- Official Correspondent:

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Regulatory Affairs & Quality Assurance
Olympus America Inc.
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- Manufacturer:

Shirakawa Olympus Co., Ltd.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No.: 3002808148

2 Device Identification

- Device Trade Name: UPD-Y0003
- Common Name: ENDOSCOPE POSITION DETECTING UNIT
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology
- Product Code: FDF

3 Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the primary component (part of this submission) of the ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003 and the device to which we claim substantial equivalence (predicate device).

Table 12-1 Primary Component & Predicate Device of the ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003

Subject Device (Part of this Submission)	Predicate Device	PD's 510(k) No.
ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003	Endoscope Contour Detection Device 3DX45	K002749

4 Device Description

<Device Description Summary>

This instrument has been designed to be used with Olympus endoscope systems for the detection and display of the shape of an endoscope once inserted into the patient.
The device detects the magnetic field generated by magnetic coils built directly into the endoscope or the probe inserted into the endoscope's instrument channel.

<Operating Principle of the subject device>

This device consists of the ENDOSCOPE POSITION DETECTING UNIT (UPD-Y0003) and a RECEIVER DISH (MAJ-1868). The RECEIVER DISH is connected to the UPD-Y0003 via a RECEIVER DISH CABLE (MAJ-1875 or MAJ-1927).

The ENDOSCOPE POSITION DETECTING UNIT (UPD-Y0003) supplies "driving" signals to the source coils in 1) the endoscope or probe, 2) the Hand Coil and 3) the Reference Plate. The endoscope and probe have plural source coils. The Hand Coil has one source coil. The Reference Plate has plural source coils. The driving signals are sent to each source coil. The driving signal is delivered to the endoscope or probe through a UPD CABLE (MAJ-1881). The driving signal is delivered to the Hand Coil through an integrated cable and the Reference Plate through an integrated cable.

When the source coils receive the driving signal, a magnetic field is generated. The magnetic field is then detected by the sense coils built into the RECEIVER DISH. The signals detected by each sense coil are processed in the UPD-Y0003. The UPD-Y0003 calculates the spatial coordinates for the specific source coil. This calculation is repeated for every source coil built into the endoscope or probe. The UPD-Y0003 then creates the visual image of the endoscope on the monitor, by then putting the spatial coordinates of the multiple source coils in order (distal to proximal) and connects them.

Akin to the methodology described above, the same process takes place for the reference plate and hand coil. The spatial coordinates data obtained from the source coils in the reference plate are used to create the standard plane of endoscope's position. The source coil in the "hand coil" is used to create an independent reference point in the field of view, as displayed on the video monitor.

<Fundamental technology modifications>

The following two modifications were made to the fundamental technology of the Subject Device from the Predicate Device's:

1) The mechanism to drive the source coils

2) Calculation method of the spatial coordinate of each source coil

5 Indications for Use

This instrument has been designed to be used with Olympus endoscope systems for the detection and display of the shape of an endoscope once inserted into the patient.

<Patient population>
Patients who require colonoscopy except as follows:
-Patients with a pacemaker
-Pregnant women

6 Comparison of Technological Characteristics

ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003 is basically identical to its predicate device in intended use, and similar in specifications. Comparison between the subject and predicate devices is shown in Table 12-2.

Table 12-2 Comparison of Specifications
Subject Device: ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003
Predicate Device: Endoscope Contour Detection Device Olympus 3DX45 (K002749)
Main unit

Specifications	Subject Device ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003	Predicate Device System Controller Unit X301811
Rated voltage	Voltage: 100-240V AC ±10% Frequency: 50/60Hz ±1Hz	Voltage: 120V AC ±10% Frequency: 50/60Hz ±1Hz
Power consumption	110VA	480VA
Unit composition	Monitor and receiver dish are separated.	Monitor, receiving unit and the main unit are built in one unit.
Dimensions	370(W) x 482(D) x 81(H)mm	490(W) x 500(D) x 1820(H) mm
Weight	9kg	59kg
Specification for Scope Model display	-The Display now shows the insertion portion even where a source coil is not installed, areas outside the detection area, and areas in which a source coil is broken,	-Displayed in a shaft shape or in a polygonal line graph. -The part of The insertion portion where source coil is not installed is not displayed.
Display of overlapping intersection area	Available	Not available

Scope/probe/reference plate/hand marker Connection Indicator	Available	Not available
Viewpoint indicator display	Select from the following: -Operating image model -Figure image model	Select from the following: -Operating table model -Coordinate axis model -Simultaneous display of Operating table model and Coordinate axis model
Patient data display	Patient ID, patient name, age and sex.	Patient ID
Error message display	Available	Not available
Display rotation	-Scope model is rotated by 90 degrees to left and right by one push of the switch. -Depending on the setting on the menu, scope model is rotated by every 2.5 degrees vertically and horizontally.	-Scope model is rotated by every 2.5 degrees vertically and horizontally.
Setting for the display start position of the scope model (Scope position)	-Setting method: Using external marker or the position of the distal end of the endoscope. -Display start position: Bottom center or top center of display.	-Setting method: Using external marker. -Display start position: Center of display.
Marking	Available	Not available
Background color	The user can choose from three predefined background colors.	-It is set by adjusting the RGB density.
Display of the distal end of scope model	The distal end of a scope model is displayed in yellow.	-The user can choose whether to display the distal end of a scope model in yellow or not.
Detection of the source coil wire break	Source coil wire break is detected automatically and reflected on the scope model display.	Manually input the number of the broken source coil to reflect it on the scope model display.
Change of the display mode	Display of the scope model can be set by the user: -Displayed from the bottom (standard setting) -Displayed from the top	Not available
Scope model thickness setup	Adjustable. The size of external marker changes depending on the scope model thickness.	Adjustable. The size of external marker does not change.
Show/hide information	Show/Hide various information individually.	Show/Hide information cannot be set individually. It is either show or hide all information.
Saving and recalling the setting	Save 20 presets.	Save only one preset.
Patient data	Input via a communication connector via video system center. And patient data is displayed.	Input with Ten-key pad. And patient data is displayed.
Video signal output	-Y/C: 1 -SD-SDI: 1 -XGA: 1	VGA: 1
Communication terminal	RS232C: 1	Not available
Receiving antenna input terminal	One.	Not available
Driving signal output terminal for external marker	Two.	One.
Driving signal output terminal for reference plate	Two.	One.

Safety standards	IEC 60601-1 Ed.2 IEEE Std C95.1, 2005 + Amendment 1:2010	IEC 60601-1 IEEE Std C95.1, 1999
EMC compliance	Class B	Class A
Plate cover	REFERENCE PLATE COVER MAJ-1880 is provided	Not provided
Installation on the patient:	Fasten the reference plate with a belt on the patient (body surface).	Attach the reference place on the patient's body (over the gown) with surgical tape.

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

The following standards have been applied to the ENDOSCOPE POSITION DETECTING UNIT (UPD-Y0003):

-IEC 60601-1: 1988, Amendment 1: 1991, Amendment 2: 1995
-IEC 60601-1-1: 2000
-IEC 60601-2-18: 1996, Amendment 1: 2000
-IEC 60601-1-2: 2007
-ISO 14971: 2007
-IEEE Std C95.1: 2005+ Amendment 1: 2010

8 Conclusion

When compared to the predicate device, the ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

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CENTER VALLEY PA 18034-0610

MAY 12 2011

Re: K103312
Trade/Device Name: ENDOSCOPE POSITION DETECTION UNIT UPD-Y0003
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: April 12, 2011
Received: April 14, 2011

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

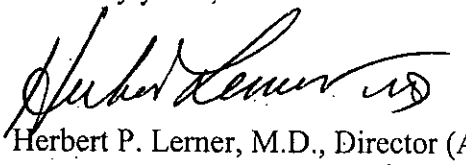
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103312

Device Name: ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003

Indications for Use:

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<Patient population>
Patients who require colonoscopy except as follows:
-Patients with a pacemaker
-Pregnant women

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103312